

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Importation
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Rene Ruiter	PERMIT NUMBER:	P526P-20-03619
ORGANIZATION:	Koppert Biological Systems, Inc.	APPLICATION NUMBER:	P526-200805-012
ADDRESS:	1502 Old U.S. 23 Howell, MI 48843	DATE ISSUED:	08/31/2020
MAILING ADDRESS:	1502 Old U.S. 23 Howell, MI 48843	EXPIRES:	08/31/2023
PHONE:	800-928-8827	FACILITY NUMBER:	N/A
ALT. PHONE:	810-632-8750	HAND CARRY:	No
EMAIL:	rruiter@koppert.com, mtacolla@koppert.com		
FAX:	810-632-8770		
DESTINATION:	2420 Celsius Ave., Suite J, Oxnard, CA 93030		
DESIGNATED PORTS:	CA, El Segundo; CA, South San Francisco; FL, Miami (Cargo, DHL, Fed Ex, UPS, etc); GA, Atlanta; NJ, Linden; NY, Jamaica; TX, Humble; WA, SeaTac		

Under the conditions specified, this permit authorizes the following:					
Regulated Article	Life Stage(s)	Intended Use	Shipment Origins	Originally Collected	Culture Designation
Bacillus amyloliquefaciens	Any	Importation for subsequent product development/efficacy trials in labs, greenhouses, or field studies. Subsequent interstate permits to be obtained for applicable movement to research/trial sites.	Netherlands (Holland)	Originally Collected from Foreign and Domestic Locations	CECT8238
Bacillus megaterium	Any	Importation for subsequent product development/efficacy trials in labs, greenhouses, or field studies. Subsequent interstate permits to be obtained for applicable movement to research/trial sites.	Netherlands (Holland)	Originally Collected from Foreign and Domestic Locations	NCIM2087 / ATCC 10778
Bacillus subtilis	Any	Importation for subsequent product development/efficacy trials in labs, greenhouses, or field studies. Subsequent interstate permits to be obtained for applicable movement to research/trial sites.	Netherlands (Holland)	Originally Collected from Foreign and Domestic Locations	NCIM2063
Paenibacillus azotofixans	Any	Importation for subsequent product development/efficacy trials in labs, greenhouses, or field studies. Subsequent interstate permits to be obtained for applicable movement to research/trial sites.	Netherlands (Holland)	Originally Collected from Foreign and Domestic Locations	MTCC7617

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Osmond Baron

DATE

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Trichoderma asperellum	Any	Importation for subsequent product development/efficacy trials in labs, greenhouses, or field studies. Subsequent interstate permits to be obtained for applicable movement to research/trial sites.	Netherlands (Holland)	Originally Collected from Foreign and Domestic Locations	KV906 / ESALQ1306
Trichoderma harzianum	Any	Importation for subsequent product development/efficacy trials in labs, greenhouses, or field studies. Subsequent interstate permits to be obtained for applicable movement to research/trial sites.	Netherlands (Holland)	Originally Collected from Foreign and Domestic Locations	AGR12
Trichoderma harzianum	Any	Importation for subsequent product development/efficacy trials in labs, greenhouses, or field studies. Subsequent interstate permits to be obtained for applicable movement to research/trial sites.	Netherlands (Holland)	Originally Collected from Foreign and Domestic Locations	M10

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

This permit does not authorize hand-carry or movement of the regulated materials/organisms via passenger baggage into the United States.

DHS CBP INSPECTORS - SHIPMENT BY BONDED CARRIER

- 1) Confirm that the carrier of the shipment imported under this USDA PPQ 526 permit is commercially bonded.
- 2) Confirm that the imported shipment has a valid USDA PPQ Form 599 Red/White label attached to the exterior for routing to a USDA APHIS PPQ Inspection Station or other "Designated Port" as stated on the Permit. A valid label will have the permit number, expiration date, label number, and address of a USDA APHIS PPQ Plant Inspection Station/Designated Port. PLEASE NOTE: In the event of a shipment of bulk container with discrete units, a single PPQ Form 599 Red/White label may be used.
- 3) Validate the permit in ePermits using the CBP search feature.
- 4) If a valid PPQ Form 599 Red/White label is not attached to the exterior of the package or the label has been covered or is otherwise not legible, then forward to the nearest USDA APHIS PPQ Plant Inspection Station.
- 5) If the address on the airway bill does not match the address on the PPQ Form 599 Red/White label then forward the package to the nearest USDA APHIS PPQ Plant Inspection Station/designated port shown on the PPQ Form 599 label. All costs associated with rerouting misaddressed packages will be assumed by the permit holder.

APHIS PPQ INSPECTORS at PIS - Low Risk

Follow the instructions in the Plant Inspection Station Manual for Low Risk Organisms - Arthropods or Microbials Red and White Labeled Packages (may be opened outside a biosafety cabinet; see procedures for handling on page 3-7-42). For questions or concerns, contact USDA APHIS PPQ in Riverdale, MD, at 301-851-2046, toll free 866-524-5421.

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PERMIT GUIDANCE

- 1) Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury; please refer to <https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>
- 2) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.
- 3) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.shtml
- 4) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 5) This permit DOES NOT fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 6) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

USDA-APHIS issues this permit to Rene Ruiter of Koppert Biological Systems, Inc. in Howell, Michigan. This permit authorizes the importation of pure cultures of the listed organisms from Koppert B.V., Netherlands to Koppert Oxnard, 2420 Celsius Ave. in Oxnard, California.

This permit authorizes use of the regulated materials/organisms for coordinating greenhouse and field research. There is to be no further movement or distribution of organisms without prior approval from State and Federal regulatory officials. Any movement of the treated materials off-site requires separate authorizations from USDA APHIS (PPQ 526 permit). This permit further authorizes Melissa Tacolla in Oxnard, California will be the recipient of the regulated organisms listed on this permit.

1. • This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.

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- The permit number or a copy of the permit must accompany the shipment.
- You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
- You are legally responsible for complying with all permit requirements and permit conditions.
- The regulated material and shipping container(s) are subject to inspection by officials of Custom and Border Protection (CBP) and APHIS. CBP or APHIS officials may require the shipment to be treated, seized, re-exported, or destroyed (in part or whole). You will be responsible for expenses.
- If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
- Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,

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- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification.


- This permit does not authorize movement or use of organisms listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. For a complete list of Select Agents please visit: <https://www.selectagents.gov/selectagentsandtoxinslist.html>
Select agents include: *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*), *Ralstonia solanacearum*, *Rathayibacter toxicus*, *Sclerophthora rayssiae*, *Synchytrium endobioticum*, *Xanthomonas oryzae*, *Bacillus anthracis*, *Brucella abortus*, *Brucella melitensis*, *Brucella suis*, *Burkholderia mallei*, and *Burkholderia pseudomallei*.

For applicants applying for a permit for Ralstonia solanacearum non-race 3 biovar 2, an exclusion letter will need to be submitted along with the application

- All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to adhere to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

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5. Melissa Tacolla in Oxnard, California will be the recipient of the regulated organisms listed on this permit and will be authorized to use the regulated organisms to coordinate greenhouse and field research in California.
6. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
7. After PPQ issues this 526 permit, you will need to request Red/White labels (PPQ Form 599) at least 5 days in advance of your shipping date. If you applied for your permit online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to Redandwhitelabelrequest@usda.gov. All email requests must come from the permit holder or designee. If requested by the designee, the permit holder must be copied on all requests. Specify the approved port as listed on the permit and the total number of labels needed. You may request additional labels the same way.
Packages without labels on the exterior may be refused entry.


Review label instructions at:

<https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/plant-pests/or-organisms-shipping-requirements>

You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.

8. This permit does not authorize hand carrying (baggage, personal belongings, auto, etc.). Any organisms imported by these methods will be seized and destroyed.
9. All repackaging activities must occur at the destination location identified above. This location must have facilities that are adequate to prevent the unauthorized dissemination of the regulated live organisms received under this permit. Access to this facility must not be accessible to the general public.
10. Regulated materials/organisms must be stored or maintained in an area that is not accessible to the general public.
11. Records must be kept of all organisms maintained under this permit. Minimally the record will consist of the name of the organism identified to the lowest taxon possible, the country, or US state/territory, where each isolate was collected, the date the isolate was received, and the date and how the organism was devitalized. These records must be made available to Federal and State regulators upon request.

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12. • DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

Prior to disposal or reuse, you must treat all contaminated and all potentially contaminated materials by one of the following methods, either alone or in combination:

1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in a minimum of a final concentration of 0.525 percent sodium hypochlorite (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes. Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

If using an autoclave the following protocol must be used:


- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions annually and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months.

OR

The autoclave must be calibrated according to the manufacturer's instructions every two years and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks.

- d. A written record of the calibration and the biological indicator tests must be maintained.

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You must follow the manufacturer's instructions for the *Geobacillus sterothermophilus* and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.

13. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

END OF PERMIT CONDITIONS

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